HOUSE BILL 716
By Shipley

SENATE BILL 1300

By Johnson

AN ACT to amend Tennessee Code Annotated, Title 53, Chapter 10 and Title 63, relative to defining and regulating the act of therapeutic substitution.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 10, is amended by adding the following as a new part 5:

53-10-501.

(a) This part shall be known and may be cited as the "Prescription Integrity Act of 2011".

(b)

(1) This part governs therapeutic substitution of a medication, which includes dispensing a chemically different drug in place of the drug originally prescribed by a patient's physician or other prescribing health care professional. Therapeutic substitution does not include substituting a generic equivalent for the prescribed drug.

(2) Therapeutic substitution shall only be allowed with the express prior authorization of the prescribing physician or other prescribing health care professional and with notice to the patient, as provided for in §§ 53-10-503 and 53-10-504. Therapeutic substitution shall be allowed only in accordance with this part.

(3) This part does not affect substitution of a generic equivalent.

53-10-502. For the purposes of this part, unless the context requires otherwise:

(1) “Drug” or “medication” means a product regulated by the federal food and drug administration as a drug, biologic, or plasma-derived therapy;

(2) “Generic equivalent” means a drug that is the same chemical compound as another drug; has the same dosage form, strength, route of administration, and intended use; and is listed as an AB-rated equivalent in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book);

(3) “Health plan” means an entity subject to the insurance laws and regulations of this state or subject to the jurisdiction of the department of commerce and insurance that contracts or offers to contract for or enters into an agreement to provide, deliver, arrange for, or pay for health care services, including a sickness and accident insurance company, a health maintenance organization, a provider-sponsored organization, a nonprofit hospital and health service corporation, a state funded health plan, or any other entity providing a plan of health insurance, health benefits, or health services;

(4) "Notification of request for therapeutic substitution” means a written communication to a patient and to the patient’s physician or other prescribing health care professional that recommends that a patient’s medication prescribed by the prescribing health care professional be changed to a different medication that is not a generic equivalent;

(5) “Pharmacy benefit manager” means a person or entity, other than a pharmacy or pharmacist, acting as an administrator in connection with pharmacy benefits; and

(6) “Therapeutic substitution” has the meaning set forth in § 53-10-501 and does not include substitution of a generic equivalent.

53-10-503.

(a) Prior to making a therapeutic substitution in a patient's prescription, including but not limited to changes in product selection and changes in dosage, the dispensing pharmacist shall:

(1) Verbally request the patient to agree to a change to the prescription, and explain that the change cannot be made unless both the patient and the prescribing physician, or other prescribing health care professional, expressly agree to the change;

(2) Verbally describe the proposed change that would be made to the prescription, including clearly identifying the originally prescribed medication and the medication that would be substituted for the originally prescribed medication;

(3) Verbally inform the patient of the impact, if any, on the patient's out-of-pocket cost; and

(4) Verbally inform the patient of any financial incentive the pharmacy or any of its employees will receive from the change to the prescription.

(b) The dispensing pharmacy shall keep clear records regarding each therapeutic substitution proposed and each agreed to by the prescriber and the patient, and report aggregate statistics to the board of pharmacy in accordance with rules promulgated by the board under § 53-10-506(b).

53-10-504.

(a) Health plans, pharmaceutical benefit managers, and their agents shall send a notification of request for medication change to a patient and to the patient's physician or other prescribing health care professional any time the health plan or pharmacy benefit manager recommends therapeutic substitution.

(b) Such notification of request for therapeutic substitution shall:

(1) Provide all of the information identified in § 53-10-503(a) that a dispensing pharmacist must provide verbally to the patient when requesting a change;

(2) Provide information that is truthful, accurate, and non-misleading, with appropriate fair balance, as those terms are defined by the federal food and drug administration in the context of medications;

(3) Include current approved product labeling and information about risks associated with the recommended medication; and

(4) State that the patient's right to approve or disapprove the proposed therapeutic substitution includes the right to discuss the proposal with the patient's physician or other prescribing health care professional before any change takes place, or to file a grievance with the health plan or pharmacy benefit manager to seek coverage of the originally prescribed medication, if that medication is not otherwise covered.

53-10-505. Health insurance premium payors and employers responsible for paying the health care premium or portions thereof shall be notified of therapeutic substitution programs adopted by health plans and pharmacy benefit managers in any plan offered by such premium payor or employer.

53-10-506.

(a) The commissioner of commerce and insurance shall promulgate rules, in accordance with the Uniform Administrative Procedures Act, complied in title 4, chapter 5, governing notifications of requests for therapeutic substitution. Such rules shall include, but not be limited to, the following:

(1) Procedures for verifying the accuracy of any notification of request for therapeutic substitution from a health plan or pharmacy benefit manager to

ensure that the notification is truthful, accurate, not misleading, and fairly balanced;

(2) A requirement that all notifications of request for therapeutic substitution intended for patient review and any communications sent directly to the patient to educate the patient about alternatives to the medications prescribed by the patient's physician or other prescribing health care professional bear a prominent legend on the first page that states “This is not a product safety notice. This is a promotional announcement from your health plan or pharmacy benefit manager about one of your current prescribed medications.”; and

(3) A requirement that the notification of request for therapeutic substitution:

(A) Expressly state that the change involves a therapeutic substitution, not a generic substitution;

(B) Explain the difference between therapeutic substitution and generic substitution; and

(C) Provide a truthful, fair, and balanced explanation regarding the potential ramifications of the therapeutic substitution, including, but not limited to, an explanation that medications in the same therapeutic class are associated with different risks and benefits and may work differently in different patients.

(b) The board of pharmacy shall promulgate rules, in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, governing pharmacy collection and reporting of information on therapeutic substitutions proposed and those agreed to by the prescriber and the patient. Such rules shall include, but not be limited to, the categories of information regarding therapeutic substitutions that a

pharmacy must collect, and those categories of information that the pharmacy must report in an aggregated form to the board of pharmacy. Further, the agency shall develop formats for annual reporting of aggregate data on therapeutic switches and report to the legislature at least once each legislative session regarding trends.

53-10-507. Issuing, delivering, or causing to be issued or delivered a notification of request for therapeutic substitution that contains a misrepresentation or false statement or that otherwise is not in compliance with this part shall subject the violator to a civil penalty to be imposed by the board of pharmacy pursuant to its authority under title 63, chapter 10, part 3, not to exceed twenty-five thousand dollars ($25,000).

SECTION 2. This act shall take effect July 1, 2011, the public welfare requiring it.